

CLAIMS

1. A DNA molecule having a sequence consisting essentially of the nucleotides which encode amino acids 112-607 of a hepatitis E virus open reading frame 2 protein.

2. A DNA molecule having a sequence consisting essentially of the nucleotides which encode amino acids 112-578 of a hepatitis E virus open reading frame 2 protein.

3. The DNA molecule of claim 1, wherein said molecule consists essentially of nucleotides which encode amino acids 112-607 of SEQ ID NO:2.

4. The DNA molecule of claim 3, wherein the sequence of said molecule has been mutated to encode a isoleucine residue at amino acid 578.

5. A recombinant protein consisting essentially of amino acids 112-607 of a hepatitis E virus open-reading frame 2 protein.

6. A recombinant protein consisting essentially of amino acids 112-578 of a hepatitis E virus open-reading frame 2 protein.

7. A recombinant expression vector comprising a DNA molecule according to claims 1-4.

8. A method of producing a recombinant hepatitis E virus protein, comprising:

- (a) culturing a host organism containing the expression vector of claim 7 under conditions appropriate to cause expression of said protein.

9. A host organism transformed or transfected with a recombinant expression vector according to claim 7.

10. A method of detecting antibodies to hepatitis E virus in a biological sample, said method comprising:
5 contacting the sample with a protein according to claims 5 or 6.

11. The method of claim 10, wherein the biological sample is selected from the group consisting of
10 whole blood, plasma, serum, cerebrospinal fluid, tissue, urine and pleural fluid.

12. The method of claim 10, wherein IgM or IgG antibody is detected.
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13. The method of claim 10, wherein the recombinant HEV protein is bound to a solid support.

14. The method of claim 10, wherein the immune complex is detected using a labeled antibody.
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15. A kit for use in a method of claim 10 comprising: said kit comprising a recombinant HEV protein according to claims 5 or 6.
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16. The kit of claim 15 further comprising a labeled secondary antibody.

17. A pharmaceutical composition comprising the protein of claim 5 and a suitable excipient, diluent or carrier.
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18. A pharmaceutical composition comprising the protein of claim 6 and a suitable excipient, diluent or carrier.
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19. A method of preventing hepatitis E, comprising administering the pharmaceutical composition of claim 17 to a mammal in an effective amount to stimulate the production of protective antibody.

20. A vaccine for immunizing a mammal against hepatitis E infection, comprising a recombinant protein according to claim 5 in a pharmaceutically acceptable carrier.

21. A method for detecting hepatitis E virus comprising: contacting a biological sample with antibodies to a protein according to claims 5 or 6 to form an immune complex with said hepatitis E virus.

22. Anti-HEV antibodies having specific binding affinity for protein according to claims 5 or 6.

23. The antibodies of claim 22, wherein said antibodies are monoclonal antibodies.

24. A kit for preventing hepatitis E in a mammal, said kit comprising a protein according to claim 5.

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